CANE
MEDICAL TECHNOLOGY
Canè S.p.A. - Socio Unico
Direzione e coordinamento CMF S.r.l.
C.F.-P.IVA - Reg. Impr. TO: 04384410017
R.E.A. TO N. 629783
Cap. Soc. Euro 120.000,00 i.v.

K091042

Area Qualità

SINCERT
CERMET
SISTEMA DI GESTIONE CERTIFICATO
REG. N. 3506
UNI EN ISO 9001:2000
ISO 13485:2004

MAY 12 2009

EXHIBIT 2

CANÈ S.r.l.
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Rivoli-Cascine Vica (Torino) Italy
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Contact: Mario Cané, President
April 1, 2009

510(k) Summary

1. Identification of the Device:
Proprietary - Trade Name: Crono S-PID 50.
Classification Name: 80 FRN.
Common/Usual Name: Ambulatory Infusion Pump.

2. Equivalent legally marketed devices
This product is similar in function and design to the pumps cleared under 510(k) number K052217 (Crono Super PID) and K052218 (Crono PCA 50).

3. Indications for Use (intended use)
The portable Crono S-PID 50 infusion devices have been designed for use in subcutaneous infusion of prescribed liquid medicines.

4. Description of the Device
Canè s.r.l., a company that specializes in the production of ambulatory pumps, has now produced a new generation of compact pumps: Crono, a perfect combination of high technology and innovative design.

Crono S-PID 50 is an ambulatory syringe infusion pump intended for the controlled administration of liquids into the patients. This means that the pump can be worn during the infusion.

Crono S-PID 50 combines high technology with innovative design. Thanks to the small size of the pump the patients can administer the drug any time during the day without interrupting daily life or leisure activities.

Crono S-PID 50 pump uses 50 ml dedicated syringes.

Crono S-PID 50 has a particular mechanism which pushes directly on the rubber syringe piston, which makes it possible to reach a significant thrust force and high accuracy of administration.

Crono S-PID 50 administers 20 µl per impulse.
In case of occlusion, an innovative infusion control system makes it possible to proceed with the infusion automatically and, after the occlusion is eliminated, to complete it.

Crono S-PID 50 is fitted with a liquid cristal display which shows the time it takes to complete the delivery, the syringe size and the battery charge status.

5. Safety and Effectiveness, comparison to predicate device.
The results of bench, EMC, and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic	Crono PCA 50 - K052218	Crono Super PID- K052217	Crono S-PID 50
Intended Use	Subcutaneous, intravenous and epidural infusion of prescribed liquid medicines.	Subcutaneous infusion of prescribed liquid medicines.	SAME to Crono Super PID - K052217
Physical characteristics	**Crono PCA 50 - K052218**	**Crono Super PID- K052217**	**Crono S-PID 50**
Size	3.3" x 2.15" x 1.65" (84.5 x 55 x 42 mm).	3" x 1.85" x 1.14" (77 x 48x 29 mm).	SAME to Crono PCA 50 - K052218
Weight	4.85 oz (140 g) (battery included).	4.0 oz (115 g) (battery included).	SAME to Crono PCA 50 - K052218
Battery	Power Source Lithium battery (3V) of the 123 A type.	Power Source Lithium battery (3V) of the 123 A type.	SAME
Infusion per impulse	20 µl.	22 µl.	SAME to Crono PCA 50 - K052218
Flow rate accuracy	+/-3%.	+/-2%.	SAME to Crono PCA 50 - K052218
Max. Occlusion pressure	2.2 bar +/-0.8 bar.	4.5 bar +/-1 bar.	3 bar +/-1.5 bar.
Capacity	50 ml.	10 or 20 ml.	SAME to Crono PCA 50 - K052218

7. Conclusion
After analyzing both bench and user testing data, it is the conclusion of CANÈ S.p.A. that Crono pumps are as safe and effective as the predicate device, has few software differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 12 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Carlo Musso
Quality Manager
Cane S.p.A.
Via Pavia, 105/I 10090
Rivoli-Cascine Vica (Torino)
ITALY

Re: K091042
Trade/Device Name: Crono S-PID 50
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: April 9, 2009
Received: April 15, 2009

Dear Mr. Musso:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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j) Indications for Use

510(k) Number (if known): _____

Device Name: Crono S-PID 50.

Indications For Use: the Crono S-PID 50 has been designed for use in subcutaneous infusion of prescribed liquid medicines.

Prescription Use **X** . AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for LCDR, Colburn 05/11/09

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091042